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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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MERCK AND CO., INC
P O BOX 2000
RAHWAY, NJ 07065-0907

EXAMINER
WEHBE, ANNE MARIE SABRINA

ART UNIT	PAPER NUMBER
1633	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/888,304	EVANS, ROBERT K.	
	Examiner	Art Unit	
	Anne Marie S. Wehbe	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *14-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13 and 21-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response to the restriction requirement received on 5/07/07 has been entered. Claims 1-26 are pending in the instant application. Applicant's election with traverse of the subject matter of Group I, claims 1-13, and 21-26 is acknowledged. Claims 14-20 are therefore withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 5/7/07, see below. Therefore, claims 1-13 and 21-26 are currently under examination. An action on the merits follows.

Election/Restrictions

As noted above, the applicant has elected with traverse the invention of Group I. The applicant argues that the search for art relating to the vaccine formulation of Group I would uncover art pertaining to the uses of the formulation claimed in Group II. This is not persuasive as the restriction requirement indicated that the products claimed in Group I can be used in methods other than those claimed in Group II. Further, it is noted that restriction for examination purposes as indicated is proper because the inventions of Groups I and II are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

However, it is further noted that where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be

amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Therefore, for the reasons set forth above, applicant's traversal is not found persuasive and the restriction requirement is still deemed proper and made FINAL.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 5/10/07 is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the information disclosure statement has been considered by the examiner and an initialed copy of the 1449 is attached to this action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-12, and 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/04932 (1996), hereafter referred to as Balasubramanian et al., in view of WO 97/25072 (1997), hereafter referred to as Engler et al.

Balasubramanian et al. teaches high molecular weight nonionic polyoxyethylene/ polyoxypropylene block copolymers of the general formula $HO(C_2H_4O)_a(C_3H_6O)_b(C_2H_4O)_aH$, where the molecule weight of the hydrophobe is between approximately 7000 and 20000 Daltons and (a) represents a number such that the percentage of polyoxyethylene hydrophile is between approximately 1% and 40% by weight (Balasubramanian et al., page 5). Balasubramanian et al. further teaches copolymers where the molecule weight of the hydrophobe is between approximately 9000 and 15000 Daltons, or 10000 to 140000 Daltons, and in particular the copolymer CL1005 where the molecule weight of the hydrophobe is approximately 12000

Daltons (Balasubramanian et al., page 13 and 22). Balasubramanian et al. also teaches DNA vaccine compositions comprising polynucleotides, a high molecule weight block copolymer such as CL1005 and a nonionic surfactant such as Tween 80 (Balasubramanian et al., pages 8, 14, and 51-52). Balasubramanian et al. teaches that the high molecule weight block copolymers described in their publication exhibit surfactant and adjuvant properties and demonstrate the ability to enhance both humoral and cellular immune responses to antigen (Balasubramanian et al., pages 5, 14, and the working examples).

Balasubramanian et al. differs from the instant invention by not teaching the further inclusion of a cationic surfactant in the compositions comprising polynucleotides and high molecular weight block copolymers. Engler et al. supplements Balasubramanian et al. by teaching that cationic detergents, a class of surfactants, can enhance the delivery of nucleic acids to cells (Engler et al., pages 4-5, and 20-21). Engler et al. further teaches the specific cationic detergents benzalkonium chloride and cetylpyridium (Engler et al., page 5, paragraph 2, and page 15). Therefore, based on the motivation to use a cationic detergent to enhance delivery of a nucleic acid as taught by Engler et al., it would have been *prima facie* obvious to the skilled artisan at the time of filing to include a cationic detergent in the compositions of Balasubramanian et al. comprising polynucleotides, a high molecular weight block copolymer adjuvant, and optionally a nonionic surfactant, in order to enhance delivery of the polynucleotides. Further, based on the high degree in skill in molecular biology and the detailed disclosures of both Balasubramanian et al. and Engler et al, the skilled artisan would have had a reasonable expectation of success in making a composition comprising polynucleotides, a high molecular weight block copolymer and a nonionic surfactant as claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-4 and 23-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 3 and 23 recite the phrase that the molecule weight of the hydrophobe “is between approximately 9000 Daltons" and claims 4 and 24 recite the phrase that the molecule weight of the hydrophobe “is between approximately 12000 Daltons". The use of the word “between” indicates a range; however, as only one molecule weight follows the phrase "between", the range is not fully set forth such that the claim is confusing and the metes and bounds cannot be determined.

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 13 recites a vaccine formulation selected from the group consisting of "D118, D118a, and D121". However, reference to formulations as "D118, D118a, and D121" is indefinite as these terms appear to be random alphanumerical codes assigned to various experimental formulations listed in either Tables 2 or 6 in the specification. The terms by themselves do not have any intrinsic meaning, nor are these terms specifically defined in the specification. In particular, the composition of each of these formulations is not clear, including whether or not a polynucleotide or specific polynucleotide is included in "D118”, “ D118a”, or “D121". It is suggested that the applicant amend the claims to recite particular ingredients and their concentrations.

No claims are allowed.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. If the examiner is not available, the examiner's supervisor, Joseph Woitach, can be reached at (571) 272-0739. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197. Representatives are available daily from 6am to midnight (EST). When calling please have your application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

/Anne Marie S. Wehbé/
Primary Examiner, A.U. 1633